04.28.00

A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.: P-9056.00
Express Mail No.: EL084630286US

First Named Inventor : Kevin McIntosh et al
Title: FLUID OXYGENATOR WITH ACCESS PORT

CERTIFICATE UNDER 37 CFR SECTION 1.10: I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope address "EXPRESS EL084630286US addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this filing date

Kathleen A. Paron
Printed Name

Kathleen A. Paron 4/24/2000
Signature

BOX PATENT APPLICATION
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

We are transmitting the following:

X **Patent Application Transmittal**
_ **Specification**
Total Pages: ___ (cover/title page 1 sheet; specification ___ sheets; claims ____ sheets; abstract 1 sheet)
X **Drawings**
Total Sheets: 5 (_ formal; X informal)
_ **Combined Declaration and Power of Attorney:**
_ Newly executed (unsigned)
_ Copy from prior application
_ Deletion of inventor(s) -- signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
_ Incorporation by reference -- *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference herein.*
_ **Accompanying application parts:**
_ Assignment of the invention to Medtronic, Inc.
_ Information Disclosure Statement
_ Copies of IDS citations
_ Preliminary Amendment
_ A copy of the Petition or Condition Petition for Extension of Time in the prior application
X Return postcard

IF A CONTINUING APPLICATION:

_ Continuation _ Divisional _ Continuation-in-Part of prior application no. __.

_ Amend the specification by inserting before the first line the sentence: This application is a _ Continuation _ Divisional _ Continuation-in-Part of application number _ filed _.

_ Cancel in this application original claims _ of the prior application before calculating the filing fee. (At least one of the original independent claims must be retained for filing purposes.)

_ The prior application is assigned of record to Medtronic, Inc.

_ The Power of Attorney in the prior application is to: _____.

_ **This application claims the benefit of U.S. Provisional Application(s) Serial No..**

X Address all future correspondence to:
Michael J. Jaro
Reg. No. 34,472
Medtronic, Inc. MS 301
7000 Central Avenue NE
Minneapolis, MN 55432
Telephone: (612) 514-3279

FEE CALCULATION

	No. Of Claims Filed	Claims Included in Base Fee	No. Of Extra Claims	Rate	Fee
Total Claims	25	20 =	5	x $18	$ 325.00
Independent Claims	3	3 =	0	x $78	$ 0.00
Multiple Dependent Claim(s)		0 =		+ $ 270	
Basic Filing Fee			0		$760.00
				TOTAL	**$1085.00**

X Charge Deposit Account No. 13-2546 the sum of $1,085.00 (Filing Fee) and $ for Assignment recordation fee for a total of **$1,085.00**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

1/27/00
Date

[signature]
Michael J. Jaro
Attorney Reg. No.34,472
Medtronic, Inc. MS 301
7000 Central Avenue NE
Minneapolis, MN 55432
Telephone: (612 514-3279

PATENT

ATTORNEY DOCKET: P- 9056.00

APPLICATION FOR UNITED STATES LETTERS PATENT

for

FLUID OXYGENATOR WITH ACCESS PORT

by
Kevin McIntosh
Bruce Jones

ATTORNEY OF RECORD:

Michael J. Jaro
Attorney Registration No.30,606
MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone: (612)514-3279
Facsimile: (612) 514-3233

CERTIFICATE OF EXPRESS MAIL

Mailing Label No.:EL084630286US

Date of Deposit: April 27 2000.

I hereby certify that this paper or fee is being deposited with the United States Postal Service as 'EXPRESS MAIL" POST OFFICE TO ADDRESSEE" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington D.C. 20231

Kathleen A. Paron

FLUID OXYGENATOR WITH ACCESS PORT

FIELD OF THE INVENTION

This invention relates to devices that oxygenate and remove carbon dioxide from fluid, including blood. The invention further relates to devices that regulate the temperature of and debubble fluid as it passes through the device.

BACKGROUND OF THE INVENTION

Typical blood oxygenators may be used as artificial cardiorespiratory devices, for example, during cardiopulmonary bypass surgery. Such oxygenators serve as an artificial respiratory system for a patient at a time when the patient is unable to rely on his own respiratory system, e.g. during surgery. These devices act temporarily as a patient's heart and lungs, circulating, adding oxygen to and removing carbon dioxide from a patient's blood while the patient's own heart and lungs are inactive.

It follows that a desirable oxygenator approximates as closely as possible the conditions and components of a patient's respiratory system. Forces mechanically applied to the blood as it flows through the oxygenator, which most closely simulate those normally experienced within the body, are safest and best for the patient's welfare.

Thus, the ambient conditions of existing oxygenators are designed to facilitate careful monitoring during use. For example, the Affinity™ Oxygenation System from Medtronic is clear so that the fluid flowing through the system can be monitored. It is also advantageous that conditions within an oxygenator can be adjusted so that they better resemble those normally experienced in the patient's body. To this end, typical oxygenators may be attached to other components of an oxygenation system, such as adjustable pumps to regulate the flow of blood through the oxygenator or an integrated heater, or cooling

device to keep the blood at a desired temperature. Generally, during bypass surgery, the principal blood handling components of an artificial respiratory system would include an oxygenator, an arterial filter and a venous reservoir. These components are generally single-use disposable products.

One condition present in a typical oxygenator that deviates from the normal conditions of the patient's body is the presence of air bubbles in the fluid as it enters the oxygenator. Generally, air is present in an oxygenator before it is used for the first time. This air continues to be present when fluid is first put into the oxygenator and may appear as bubbles in the fluid. Under typical circumstances, the bubbles are removed during the priming of the device. Usually, removal of air bubbles occurs on the distal side of the fiber bundle. Then, any air bubbles on the proximal side must be forced through the fiber bundle to the distal side in order to be removed. Biocompatible coatings and the presence of blood in the device make removal of the air bubbles difficult, as they are unlikely to pass through the fiber wall or through the fiber bundle to the distal side.

These bubbles can cause a number of difficulties in that they may physically obstruct the actual flow of the fluid through the device. The bubbles could also potentially pass through the device and be sent back to the patient, which could cause injury to the patient.

Therefore a means of debubbling the fluid on the proximal side of the fiber bundle is desirable. Furthermore, a means that could be used to access the blood as it enters the oxygenator would be desirable.

SUMMARY OF THE INVENTION

One aspect of the present invention provides a fluid oxygenating apparatus or oxygenator which includes a housing defining a chamber, a core within the chamber, the core including a channel, and a bubble release port communicating with the channel. This oxygenator may be arranged so that fluid may be flowed through the channel and bubbles may be released through the bubble release port. This bubble release port may be formed in a cap portion of

the oxygenating apparatus. The oxygenating apparatus may also include an arrangement of fibers that facilitate fluid oxygenation. Other items, such as a heat exchanger, a hemoconcentrating device, a sampling device, or a pump, may be attached to the fluid oxygenating apparatus. The bubble release port may have a variety of structures including, but not limited to, a dome-like structure, a toroidal structure, or a helical structure.

Another aspect of the present invention provides a method of debubbling a fluid oxygenating apparatus. This method includes flowing fluid through an inlet end of a channel within the apparatus, collecting bubbles adjacent an outlet end of the channel, and releasing bubbles through the bubble release port. The method may include flowing the debubbled fluid through the fiber arrangement described above. The method may also include accumulating the bubbles in a structure such as a dome-like structure, a helical structure, or a toroidal structure. The method also provides for attaching such devices as a heat exchanger, a sampling device, a hemoconcentrator or a pump to the fluid oxygenating apparatus.

Another aspect of the present invention includes a fluid oxygenating apparatus with a housing that defines a chamber, a core positioned within the housing, a manifold formed within the core, a fiber bundle positioned around the core, and a bubble release port. The apparatus is arranged so that when bubbles accumulate in the apparatus as fluid flows through, the bubbles may be released through the port.

The foregoing, and other, features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims in equivalence thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a vertically oriented first embodiment of a fluid oxygenator in accordance with the present invention;

FIG. 2 is a top view of the fluid oxygenator of **FIG. 1**;

FIG. 3 is a cross-sectional view of the vertically oriented fluid oxygenator of **FIG. 1** showing the flow of three different fluids through the oxygenator;

FIG. 4 is a partial cross-sectional view of a second embodiment of a fluid oxygenator in accordance with the present invention; and

FIG. 5 is a partial cross-sectional view of a third embodiment of a fluid oxygenator in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

FIG. 1 illustrates a preferred embodiment of a blood oxygenator **10** in accordance with the present invention. Blood oxygenator **10** comprises a housing **12**, which has a generally cylindrical outermost peripheral wall, open at both ends prior to assembly of the oxygenator **10**. The housing **12** surrounds a core **14**, which is also generally cylindrical. Within the core lies a manifold **16**. A space **18** lies between the core and the manifold.

A fiber bundle **17** is wrapped around core **14**. The fiber bundle **17** comprises a number of microporous fibers wound around the core **14**. The core **14** has a first end, a second end and an axis extending from the first to the second end. The fiber bundle **17** extends radially outward relative to the axis of the core. Each of the fibers in the bundle **17** may preferably include a first end and a second end, a hollow interior and a semi-permeable wall. The fibers may also be coated with a biocompatible protein coat. Preferably the first ends of the fibers are adjacent the first end **24** of core **14** and the second ends of the fibers are adjacent the second end **34** of core **14**.

Potting means **26**, **27** are located at the end of said fibers. These potting means are typically adhesive means, for example a polyurethane adhesive, that seal the fibers. Potting means **26** are located adjacent the first end **24** of core **14** and preferably seal the first ends of the fibers. Potting means **27** are located adjacent the second end of core **14** and preferably seal the second ends of the fibers. Potting means **26**, **27** also adhere to housing **12**. Additionally potting means **26**, **27** serve to separate the fluid phase from the gas phase within the oxygenator. A circumferential rib and window array **29** is located at the first end **24** of core **14**.

A cap **40** is fitted at the top of the oxygenator **10** and generally includes a gas inlet **42**. Cap **40** may be detachable from the oxygenator **10** or, as in the embodiment of **FIG. 1** may be molded to oxygenator **10**. A recirculation port **44** may be suitably located on oxygenator **10**, for example, as seen in **FIG. 1**, adjacent cap **40** and through housing **12**.

As shown in **FIGS. 1** and **2**, cap **40** also includes a bubble release port or access port **46**. In one embodiment, access port **46** may be attached to the gas cap **40**. In a second embodiment, the access port **46** is molded into gas cap **40**. Alternatively, access port **46** may be a rigid or flexible tube or pathway that allows access to manifold **16** through the cap **40** or housing **12**. When oxygenator **10** is in a typical vertical orientation, access port **46** allows access to the section of oxygenator **10** above potting means **26**. Access port **46** may further allow access to the outer surface of core **14**.

The gas cap **40** with access port **46** is mated to potting means **26**, and thereby attached to oxygenator **10** as a whole, via mating feature **48**.

Oxygenator **10** further includes a suitably located blood outlet **28**. Outlet **28** may, as shown in **FIG. 1** be located through housing **12** and adjacent the second end **34** of core **14**.

The bottom of the oxygenator **10** is received in base **50**. Base **50** includes gas outlet **52** and a suitably located blood entrance **54** for providing blood flow into oxygenator **10**. It is contemplated that base **50** may be removably or permanently attached to the bottom of oxygenator **10**.

Oxygenator **10** may also be attached to or carry a heat exchanger **60**. A fluid type heat exchanger is depicted in **FIG. 1** with an inlet **62** and an outlet **64**, but other suitable heat exchange devices may be incorporated with oxygenator **10**. In the embodiment shown in **FIG. 1**, for example, heat exchanger **60** is attached to oxygenator **10** and blood entrance **54** is incorporated into exchanger **60**.

Oxygenator **10** may further be attached to other appropriate pumping or cooling or heating systems. Generally, a pumping system (not shown), such as, for example a peristaltic or centrifugal pump, is attached to oxygenator **10**. Typically, oxygenator **10** is further attached to a reservoir, which provides blood to the oxygenator. The pumping system operates at sufficient pressure to send the blood from the reservoir, through the oxygenator **10** and eventually back to the patient. The value of this pressure is typically between 200 and 760 mm Hg, even more typically between 300 and 700 mm Hg although any pressure sufficient to send the blood on the above-described circuit is acceptable.

The oxygenator may be generally operated in a vertical position, such as that depicted in **FIGS. 1** and **3**. Referring to **FIG. 3**, the paths of three fluids, where fluid may be a liquid or gas, are illustrated. Solid white arrows **70** indicate the path of a fluid to be oxygenated, for example, blood. Solid black arrows **71** indicate the path of an oxygenating fluid, for example, oxygen. Dotted black arrows **72** indicate fluid in a heat exchanger, for example, water.

A fluid to be oxygenated, such as blood, is introduced into manifold **16** of the core **14** through the entrance **54** and flows up through manifold **16** toward the circumferential rib and window array **29** at the first end **24** of the core **14**. This first end **24** is also where mating feature **48** meets potting means **26**. The

blood flows through the array **29** filling space **18** that surrounds an outer surface of the core **14**.

From the manifold **16** the blood then flows radially away from the core **14**, all along the length of the outer surface of the core **14** between upper potting means **26** and lower potting means **27**.

The blood flows through the fiber bundle **17** and eventually exits the oxygenator **10** through the blood outlet **28**. Fiber bundle **17** may be coated with a biocompatible protein coating. Fluid introduced into the oxygenator other than blood, such as priming fluid, will flow in the same manner described above.

Bubbles may be entrained in the fluid as it flows along this path. The bubbles are often carried from the blood reservoir or may form in the blood pump before it enters the blood inlet **54**. Additionally, a priming fluid may be sent along the path before the blood is circulated through it. This priming fluid, typically a saline solution, may also carry bubbles from the reservoir or pump to the oxygenator inlet **54**.

As the fluid flows through the fiber bundle **17**, some of the bubbles may be unable to pass through the bundle **17**. These bubbles accumulate within manifold **16** and core **14**. These bubbles may block the blood flow path and may, if enough accumulate, retard the function of the oxygenator **10**. Such accumulation of bubbles may occur particularly when the fibers are coated with a biocompatible material or coating.

The access port **46** allows access to manifold **16** and core **14** and provides means for debubbling the blood before it flows through the fiber bundle **17**. In one typical method of operation, the pressure of the blood flowing through the oxygenator **10** is not sufficient to push blood out through access port **46**. Rather, the pressure is just sufficient to send the blood flowing out of the array **29** at the top of core **14**. The bubbles may tend to accumulate near this array **29**, and elsewhere near the top of core **14,** which brings them near the end of access port **46** that is mated to the core **14**. From here, the bubbles may thus tend to disperse and may be released via the access port. The oxygenator **10** may be agitated to induce bubbles that accumulate in other areas of the flow

path to move near the access port **46** and then be released. The access port allows the naturally buoyant bubbles a release path from the oxygenator **10**.

In addition to providing this release path, access port **46** may also serve as a means to access the oxygenator **10** and the fluid flowing through the oxygenator while the oxygenator is in use. As seen in **FIG. 3**, this makes the fluid accessible before it passes through the fiber bundle **17**.

As only one example, the access port **46** may be used as a blood supply site for a hemoconcentrator **82**. A hemoconcentrator **82** may be attached to access port **46** so that the blood flows through the hemoconcentrating device **82**. Additional pumping means may or may not be necessary to facilitate this additional flow. In a typical artificial circulation system, the hemoconcentrator is usually attached to recirculation port **44** of oxygenator **10**. Additional attachment and pumping means (to provide sufficient pressure to move the blood through the hemoconcentrator **82**) may be necessary in order for recirculation port **44** to continue its existing function and, at the same time, divert blood to the hemoconcentrator **82**. However, when access port **46** is used as a blood supply port, an attached hemoconcentrator may rely on the already established pumping flow of oxygenator **10** as described above; this may eliminate the necessity for separate pumping means specific to the hemoconcentrator. Moreover, recirculation port **44** is left free to continue its recirculation function.

Occasionally, the blood flowing through the system is sampled. Usually, blood is sampled from the reservoir. Using access port **46** of the present invention, however, blood may be sampled as it is flowing through the oxygenator **10**, thereby providing a more accurate sample. The same is true of pressure monitoring using access port **46** to monitor the blood in the manifold **16** and within the core **14**. Any suitable sampling device **482,** such as, for example, one that measures blood pressure or one which measure oxygenation levels, may be attached to access port **446** as indicated in **FIG. 4.**

Additionally, access port **46**, if left open, can serve as a continuous purge port, providing a continuous means to purge air from the blood as it flows through the oxygenator **10**.

Meanwhile, as shown in **FIG. 3**, a second fluid to provide oxygenation flows along the fluid path indicated by the solid black arrows **71**. In this path, a gas, such as, for example, oxygen, enters the oxygenator **10** through the gas inlet **42** and flows into and through the hollow fibers comprising the bundle **17** and finally exits via the gas outlet **52**. Gas exchange takes place via diffusion through micropores in the hollow fibers. This occurs as the blood is flowing radially through the fiber bundle **17** at the same time oxygen is flowing in a direction generally perpendicular to the blood.

If, as shown in **FIG. 3**, oxygenator **10** has an attached heat exchanger, a third fluid, such as water, flows along within a path in the heat exchanger **60** (designated by the dotted black arrows **72**). This fluid enters at **62** and exits at **64** and heats or cools the blood as desired.

Referring again to **FIG. 4**, a second embodiment of access port **446** is shown. In this embodiment access port **446** is configured so that it has a dome-shaped attachment at end **447**. In one embodiment, access port **446** may be attached to gas cap **440**. In another embodiment, the port **446** is molded into gas cap **440**. When the oxygenator is in a typical vertical orientation, access port **446** allows access to the section of the oxygenator above potting means **426**. Access port **446** also allows access to manifold **416** within the core **414**.

The gas cap **440** with attached port **446** is mated to potting means **426**, and thereby attached to the oxygenator as a whole, via mating feature **448**.

Debubbling occurs in the embodiment of **FIG. 4** in a manner similar to that described above. The dome shape allows the bubbles to accumulate within or near the dome as they flow from the manifold **416** through rib and window array **429**.

Referring to **FIG. 5**, a third embodiment of access port **546** is shown. In this embodiment access port **546** is configured so that it has a substantially toroidal or helical configuration at one end **547**. It is contemplated that access port **546** may also be configured so that the entire port has a substantially toroidal or helical configuration. In one embodiment, access port **546** may be attached to gas cap **540**. In another embodiment, the port **546** is molded into

gas cap **540**. When the oxygenator is in a typical vertical orientation, access port **546** allows access to the section of the oxygenator above potting means **526**. Access port **546** also allows access the manifold **516** within the core **514**.

The gas cap **540** with attached port **546** is mated to potting means **526**, and thereby attached to the oxygenator as a whole, via mating feature **548**.

Debubbling occurs in the embodiment of **FIG. 3** in a manner similar to that described above. The toroidal or helical shape may facilitate entrapment of the bubbles.

It should be appreciated that the embodiments described above are to be considered in all respects only illustrative and not restrictive. The scope of the invention is indicated by the following claims rather than by the foregoing description. All changes that come within the meaning and range of equivalents are to be embraced within their scope.

WE CLAIM:

1. A fluid oxygenating apparatus comprising:

a housing defining a chamber;

a core positioned within the chamber, the core including a channel formed therein, wherein the channel includes an inlet end and an outlet end; and

a bubble release port communicating with the outlet end of the channel, wherein fluid is flowed through the inlet end of the channel and bubbles are released through the bubble release port.

2. The apparatus of claim 1 wherein the housing includes a body portion and a cap portion, the bubble release port formed in the cap portion.

3. The apparatus of claim 2 wherein the cap portion is a separate member attached to the body portion.

4. The apparatus of claim 1 further comprising a plurality of fibers positioned in the chamber and surrounding the core.

5. The apparatus of claim 4 wherein the fibers are coated with a biocompatible coating.

6. The apparatus of claim 5 wherein the biocompatible coating prevents the passage of bubbles through the fibers.

7. The apparatus of claim 4 further comprising a first potting element adjacent a first end of the fibers.

8. The apparatus of claim 7 further comprising a second potting element adjacent a second end of the fibers.

9. The apparatus of claim 8 wherein the housing includes a body portion and a cap portion, the bubble release port formed in the cap portion and the cap portion attached to the first potting means via a mating feature.

10. The apparatus of claim 1 further comprising a heat exchanger operatively connected with the channel, the heat exchanger including an inlet port to receive the fluid into the heat exchanger and channel.

11. The apparatus of claim 1 further comprising a hemoconcentrating device operatively connected with the bubble release port.

12. The apparatus of claim 11 wherein fluid being flowed through the apparatus is flowed through the hemoconcentrator without additional pumping means.

13. The apparatus of claim 1 further comprising a fluid sampling device operatively connected with the bubble release port.

14 The apparatus of claim 1 wherein the bubble release port has a first end communicating with the outlet end of the channel and a second end, further comprising:

a dome-like structure at the first end.

15. The apparatus of claim 1 wherein the bubble release port has a first end communicating with the outlet end of the channel and a second end, further comprising:

a toroidal structure at the first end.

16. The apparatus of claim 1 wherein the bubble release port has a first end communicating with the outlet end of the channel and a second end, further comprising:

a helical structure at the first end.

17. A method of debubbling a fluid oxygenating apparatus comprising:

providing a housing defining a chamber, a core positioned within the chamber having a channel with an inlet end and an outlet end and a bubble release port communicating with the outlet end of the channel;

flowing fluid through the inlet end of the channel;

collecting bubbles adjacent the outlet end of the channel; and

releasing bubbles through the bubble release port.

18. The method of claim 17 further comprising:

flowing the debubbled fluid through a plurality of fibers;

oxygenating the fluid as it passes through the fiber; and

flowing the fluid out a fluid outlet formed in the housing.

19. The method of claim 17 further comprising:

accumulating bubbles in a dome portion adjacent the outlet end of the channel.

20. The method of claim 17 further comprising:

accumulating bubbles in a helical portion adjacent the outlet end of the channel.

21. The method of claim 17 further comprising:

accumulating bubbles in a toroidal portion adjacent the outlet end of the channel.

22. The method of claim 17 further comprising:

providing a heat exchanger operatively connected with the channel, and

flowing fluid through the heat exchanger.

23. The method of claim 17 further comprising:

providing a hemoconcentrator operatively connected with the bubble release port;

providing a pumping means to pump fluid through the fluid oxygenating apparatus; and

flowing fluid through the hemoconcentrator using the same pumping means.

24. The method of claim 17 further comprising:

providing a sampling device operatively connected with the bubble release port; and

sampling the fluid via the bubble release port.

25. A fluid oxygenating apparatus comprising:

a housing defining a chamber;

a core positioned within and operatively attached to the housing, the core including a manifold formed therein;

a fiber bundle positioned around the core; and

a bubble release port positioned adjacent a top end of the housing and communicating with a top end of the manifold; wherein fluid is flowed through an inlet of the manifold and out at least one opening formed in a top of the core and through the fiber bundle and through an outlet in the housing while bubbles are released through the bubble release port.

ABSTRACT OF THE DISCLOSURE

A fluid oxygenating apparatus is provided which includes a housing defining a chamber, a core positioned within the chamber including a fluid channel formed therein, and a bubble release port communicating with the outlet end of the channel. Fluid is flowed through an inlet of the channel and bubbles are released through the bubble release port. A method and system for debubbling a fluid in such an apparatus is also provided.

FIG. 1

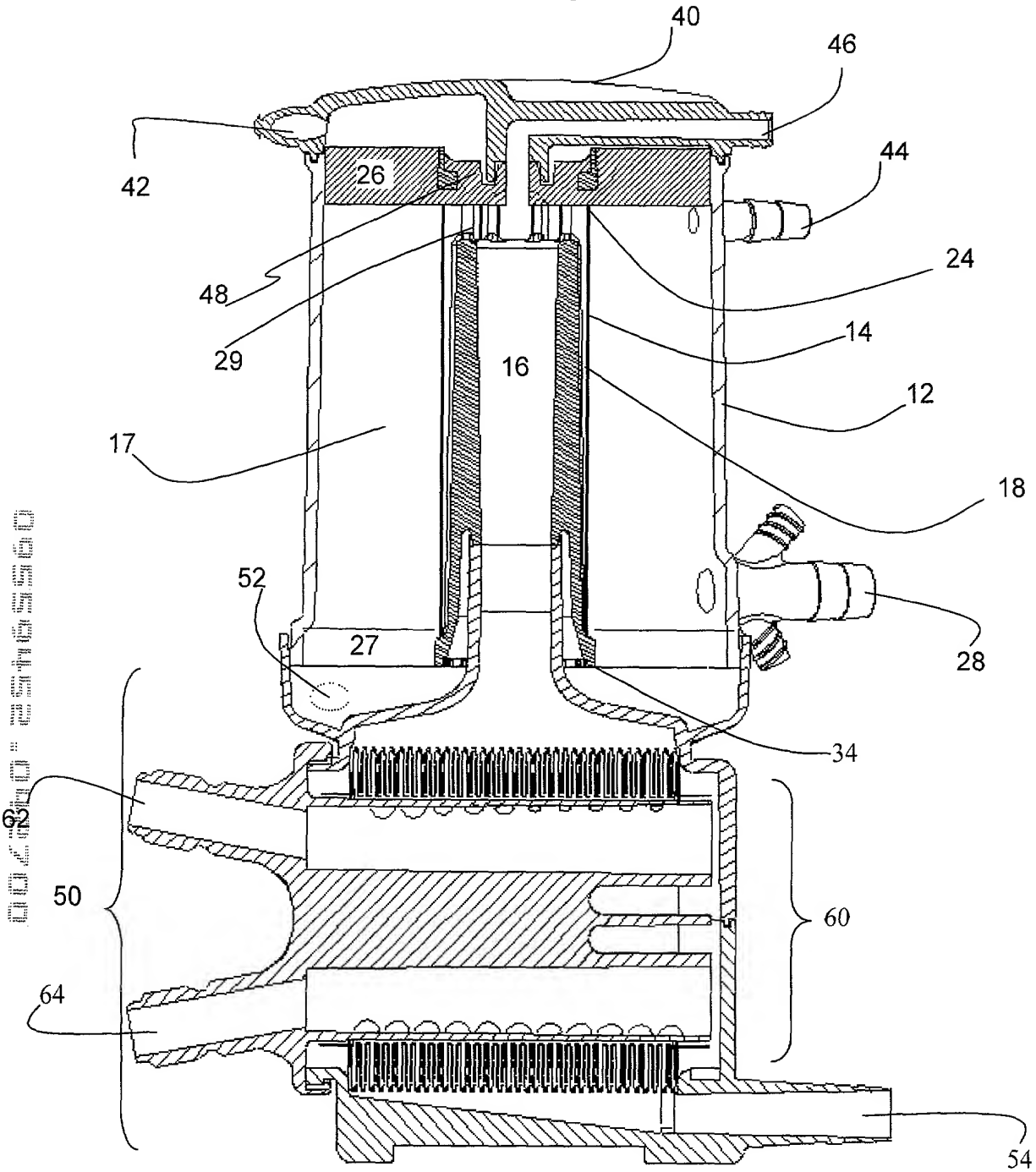


FIG. 2

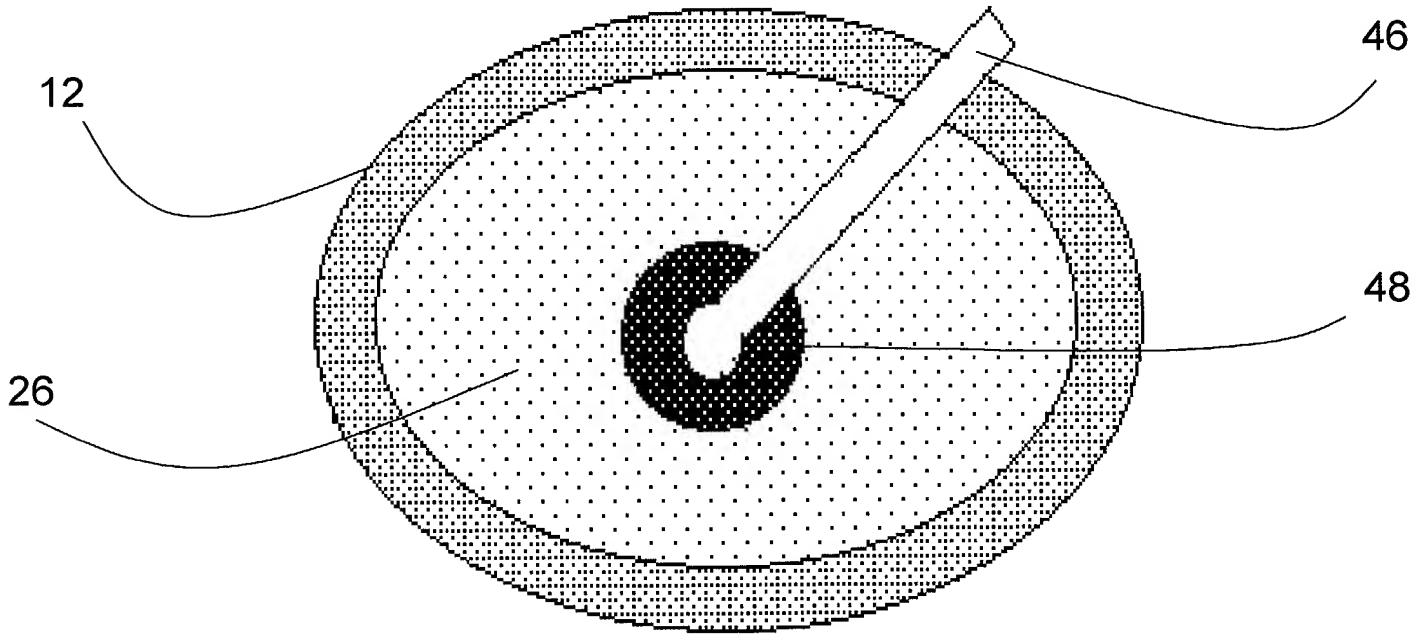


FIG. 3

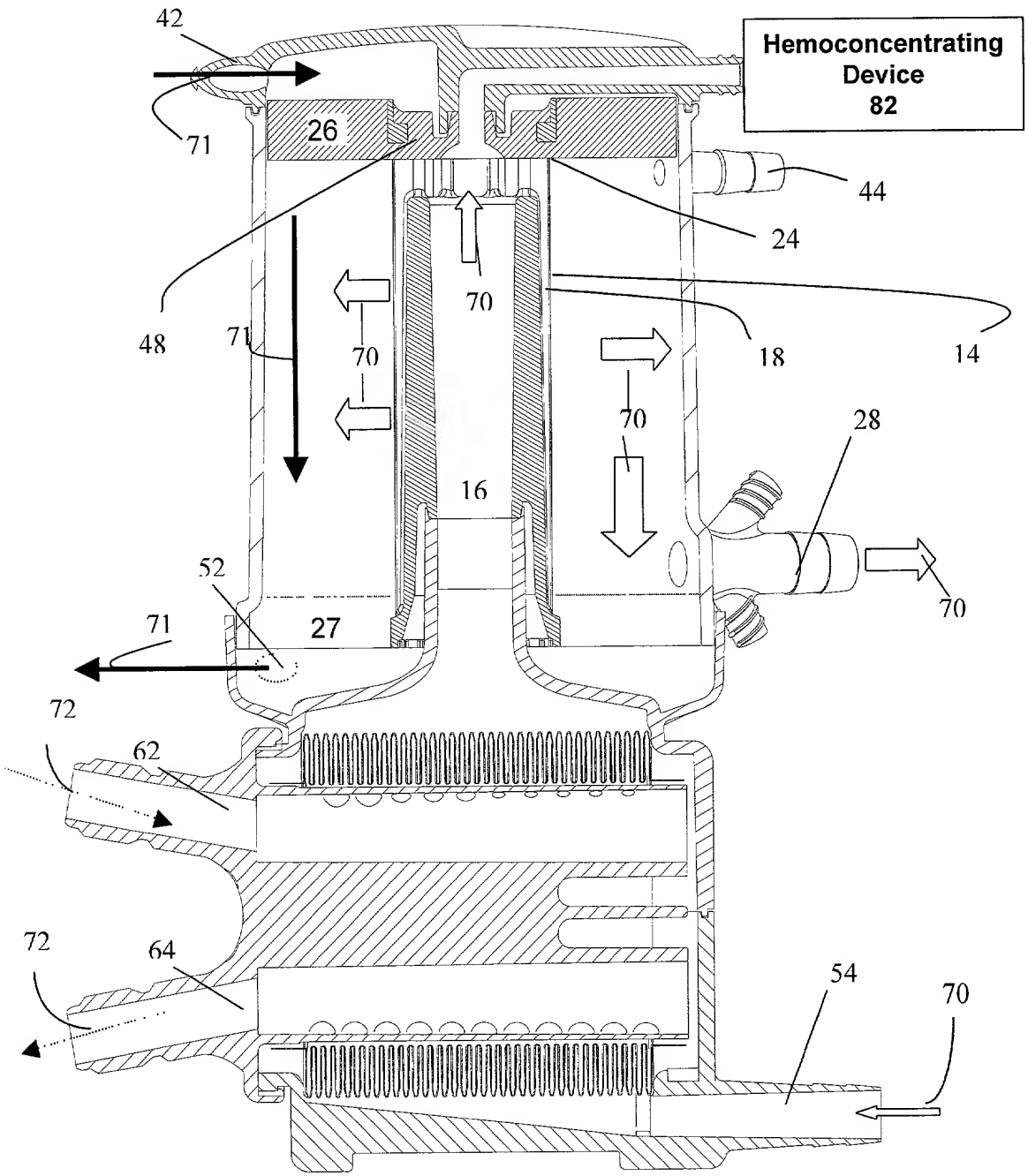

Hemoconcentrating Device 82
42
71
26
44
24
70
48
71
70
18
14
70
28
16
52
71
27
70
72
62
72
64
54
70

FIG. 4

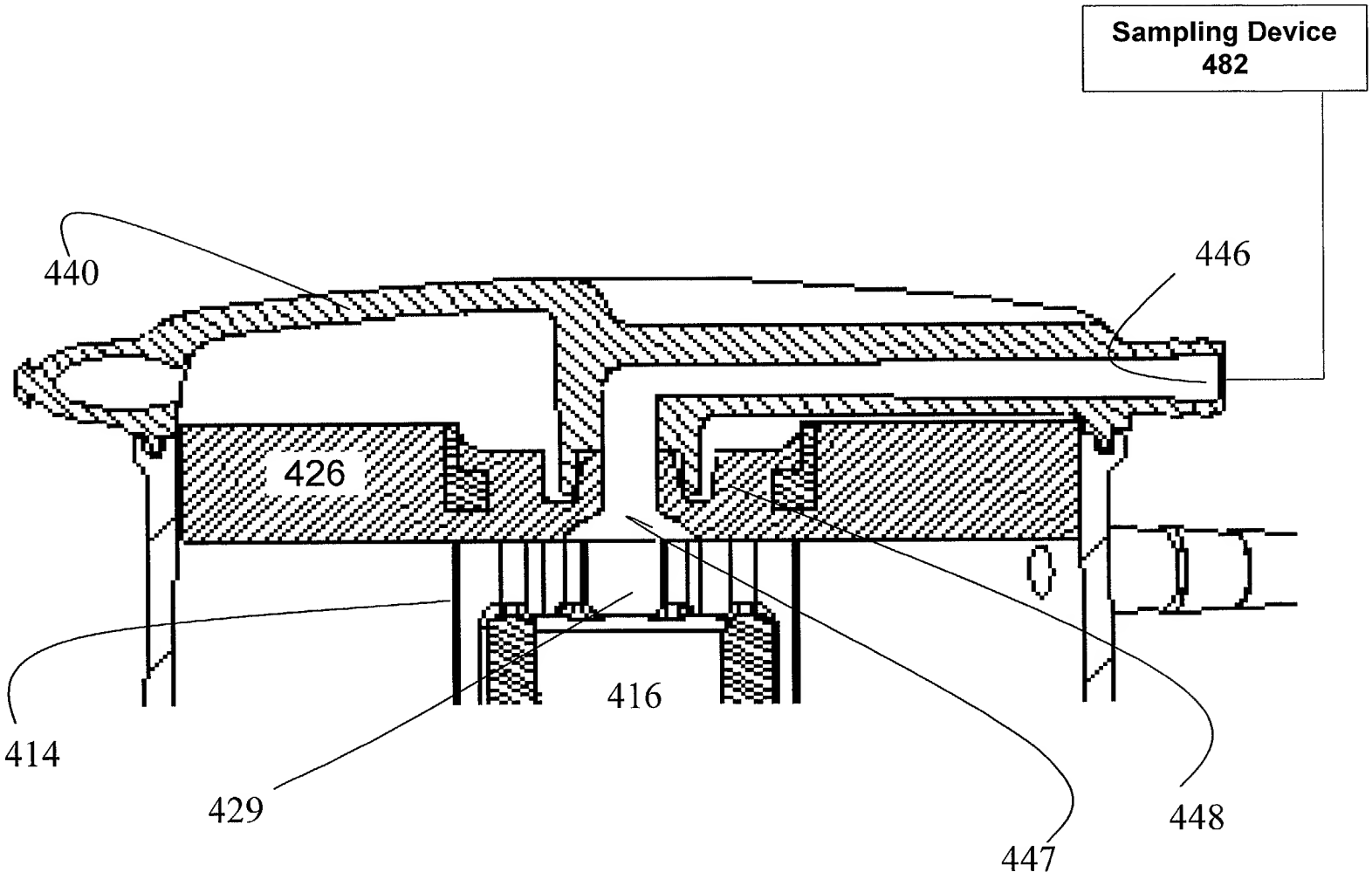
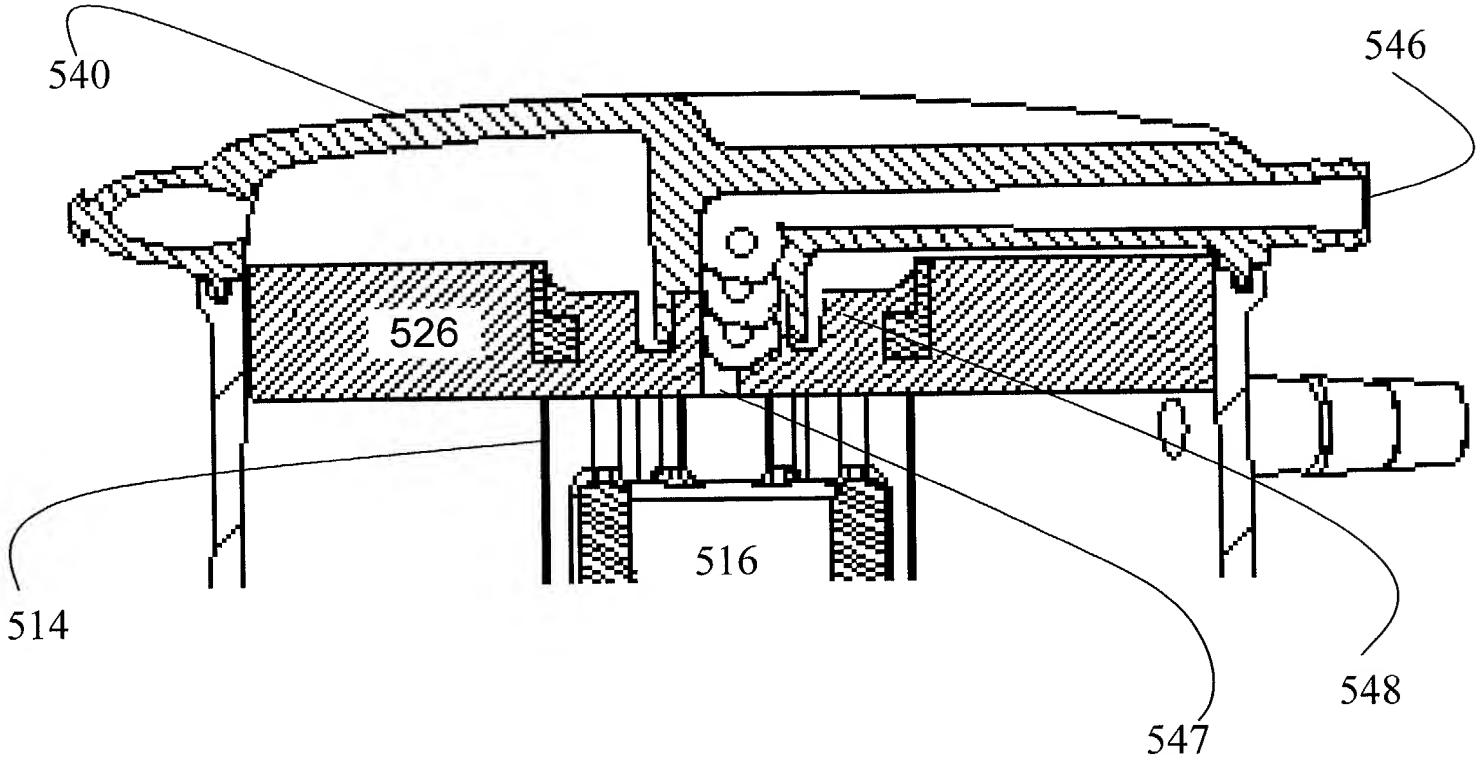


FIG. 5



P-9056.00

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence. post office address and citizenship are as stated below next to my name, that

I verily believe I am the original. first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: ***FLUID OXYGENATOR WITH ACCESS PORT***

The specification of which

a. **XX** is attached hereto

b. _____ was filed on __ as application serial no _and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no __ filed _ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification. including the claims. as amended by any amendment referred to above

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37. Code of Federal Regulations. §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed·

a. _X_ no such applications have been filed

b. ___ such applications have been filed as follows.

FOREIGN APPLICATION(S), IF ANY. CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS. IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application

[1]

§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.